UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. SANOFI BIOTECHNOLOGY SAS, SANOFI-AVENTIS AMERIQUE DU NORD, SANOFI-AVENTIS U.S. LLC, and GENZYME CORPORATION, Defendants.	Case No. 7:24-cv-08751 JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") sues Defendants Sanofi Biotechnology SAS, Sanofi-Aventis Amerique du Nord, sanofi-aventis U.S. LLC, and Genzyme Corporation, and alleges as follows:

I. INTRODUCTION

1. Regeneron and Defendants jointly commercialize a breakthrough medicine discovered by Regeneron scientists — Dupixent® (dupilumab) ("Dupixent"). Dupixent is a transformative invention, a blockbuster success used by approximately one million patients today to treat various diseases. Since its launch, total net sales in the United States have exceeded $30 *billion*. The parties split Dupixent's profits pursuant to a Collaboration Agreement.[1] This agreement requires the cross-company teams managing Dupixent to optimize "the commercial

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[1] That agreement is the Amended and Restated License and Collaboration Agreement dated as of November 10, 2009, as amended as of May 1, 2013, July 1, 2015, April 5, 2020, October 6, 2021, and June 1, 2022 (the "LCA" or "Collaboration Agreement").

potential of and financial returns from" Dupixent "without regard to any other pharmaceutical product" of either company, and includes important checks and balances to ensure they do so.

2. To that end, the Collaboration Agreement requires Defendants to provide Regeneron with "full access to material information" related to the sales of Dupixent. That material information includes the written and oral contracts between Defendants and pharmacy benefit managers ("PBMs") and payer entities — including related group purchasing organizations and specialty pharmacies — that establish pricing, rebates, and other important terms governing the sale of Dupixent (the "PBM Agreements"). In violation of the Collaboration Agreement, Defendants have stonewalled Regeneron's repeated requests for full access to the PBM Agreements.

3. As of August 2024, nearly one million patients were being treated with Dupixent, which is FDA-approved to treat six diseases. And given Dupixent's blockbuster status, the PBM Agreements have enormous financial and commercial consequences for the parties' collaboration and bargained-for rights. The PBM Agreements' terms influence United States net sales, which exceeded $7.6 billion in the first nine months of 2024, $8.8 billion in 2023, $6.6 billion in 2022, $4.7 billion in 2021, $3.2 billion in 2020, $1.8 billion in 2019, and $776 million in 2018. The total rebates and discounts on Dupixent that Defendants have given the PBMs are estimated to be a significant fraction of the total sales. Because Regeneron and Defendants split Dupixent's profits in the United States, Regeneron effectively pays for half of these rebates and discounts.

4. By refusing to provide Regeneron with full access to the PBM Agreements, Defendants have breached the Collaboration Agreement and effectively replaced its information-sharing provision with a "trust Sanofi" provision. Defendants' breach has deprived Regeneron of critical bargained-for rights, including the right to fully participate in key commercialization decisions regarding Dupixent and the right to ensure Defendants are performing their contractual obligations. Given the magnitude of Dupixent's U.S. sales — and associated rebates and discount obligations — and the number of patients who depend on Dupixent for treatment, Defendants' misconduct not only is a breach of the Collaboration Agreement, but is also commercially unreasonable.

5. Regrettably, Defendants' malfeasance does not end there. Defendants have also stonewalled Regeneron's attempts to fully audit their books and records related to Dupixent — another right Regeneron holds under the Collaboration Agreement. Regeneron's bargained-for right to audit Defendants' books and records serves as an important safeguard, which ensures that the parties' collaboration, through which billions of dollars flow, is conducted according to the Collaboration Agreement's terms. Indeed, the partial audit Regeneron conducted most recently without access to the PBM Agreements identified a significant monetary adjustment, many multiples of $75,000, that Defendants owed Regeneron in connection with commercializing Dupixent. Examining the PBM Agreements could uncover even larger errors resulting in adjustments in Regeneron's favor.

6. Regeneron's right to see the PBM Agreements helps ensure Defendants are complying with other provisions of the Collaboration Agreement as well. Defendants have acknowledged the PBM Agreements address other Sanofi products in addition to Dupixent; indeed, that is one of Defendants' justifications for refusing to share the agreements with

Regeneron. But as noted above, under the Collaboration Agreement cross-company teams must optimize the commercial potential of and financial returns from Dupixent without regard to the companies' other products. Regeneron's representatives cannot be sure the PBM Agreements do not advantage other Sanofi products at the expense of Dupixent without seeing the PBM Agreements.

7. Defendants are wholly responsible for this dispute. Regeneron has pursued and exhausted all reasonable avenues to resolve it outside of court. Those avenues include both the dispute resolution procedures outlined in the Collaboration Agreement, and Regeneron offering creative solutions to mitigate Defendants' purported concerns going forward. Indeed, after Defendants protested that providing Regeneron with access to the PBM Agreements would disclose information about other Sanofi products, Regeneron proposed a solution for future PBM Agreements: Defendants should separate the PBM Agreements for Dupixent from the PBM Agreements for Defendants' other drugs. Defendants refused, evincing their unwillingness to resolve this dispute outside of court. Defendants' conduct has left Regeneron with no choice but to again demand that Defendants provide Regeneron and its auditors with "full access" to the multi-drug PBM Agreements. But Defendants have repeatedly refused to do so. Defendants' pattern of evasion can only raise the question, "What are Defendants trying to hide?" — and has forced Regeneron to bring this lawsuit.

8. This dispute is a straightforward one: Defendants have breached the Collaboration Agreement by refusing to provide Regeneron with full access to material information relating to the commercialization of Dupixent, and by failing to cooperate with Regeneron's contractually-authorized audit. Regeneron brings this action seeking,

among other things, an order directing Defendants to provide complete, unredacted versions of the PBM Agreements to Regeneron and its auditors.

II. PARTIES, JURISDICTION, AND VENUE

9. Plaintiff Regeneron is a corporation organized under the laws of the State of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

10. Regeneron is a publicly traded biotechnology company that invents, develops, manufactures, and commercializes life-transforming medicines for people with serious diseases. Physician-scientists founded Regeneron in 1988, and since then Regeneron has grown into a leading center of discovery and innovation. Since Regeneron’s founding, its board of directors — comprised of its founding scientists, industry experts, and Nobel laureates — has consistently pushed the boundaries of scientific excellence and discovery with a shared commitment to transforming lives. Currently, ten members of Regeneron’s thirteen-member Board hold doctorate-level degrees in medical or scientific fields, and six are members of the National Academy of Sciences. Regeneron-invented medicines help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, infectious diseases, and rare diseases. And Regeneron was the first company to obtain emergency use authorization from the federal Food and Drug Administration (“FDA”) for an antibody cocktail treatment for COVID-19.

11. Defendant Sanofi Biotechnology SAS is a *société par actions simplifiée* organized under the laws of France, having its principal place of business at 82 Av. Raspail 94250 Gentilly, France. Sanofi Biotechnology SAS is the successor-in-interest to Aventis Pharmaceuticals Inc., a signatory to the LCA.

12. Defendant Sanofi-Aventis Amerique du Nord is a partnership organized and existing under the laws of France, having its principal place of business at 174 avenue de France, 75013 Paris, France. Sanofi-Aventis Amerique du Nord is a signatory to the LCA.

13. Defendant sanofi-aventis U.S. LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi Biotechnology SAS and Sanofi-Aventis Amerique du Nord perform certain of their obligations under the LCA through sanofi-aventis U.S. LLC. *See* LCA § 20.11. For example, and upon information and belief, sanofi-aventis U.S. LLC markets Dupixent in the United States and enters into the PBM Agreements to establish pricing terms, coverage, formulary positioning, access, and other terms for Dupixent.

14. Defendant Genzyme Corporation is a corporation organized and existing under the laws of the State of Massachusetts, having its principal place of business at 450 Water Street, Cambridge, Massachusetts 02142. Sanofi Biotechnology SAS and Sanofi-Aventis Amerique du Nord perform certain of their obligations under the LCA through Genzyme Corporation. For example, and upon information and belief, Genzyme Corporation has participated in the Development and Commercialization of Dupixent, as those terms are respectively defined in §§ 1.20 and 1.35 of the LCA.

15. Regeneron, Aventis Pharmaceuticals Inc., and Sanofi-Aventis Amerique du Nord entered the LCA.

16. Defendants are all "under [the] common control" of Sanofi (a corporation organized and existing under the laws of France) for purposes of the LCA because Sanofi

owns, directly or indirectly, at least 50% of each Defendant. LCA §§ 1.2, 20.11. Accordingly, Defendants and Sanofi are all "Affiliate[s]" of each other as defined by the LCA. LCA § 1.2.

17. Defendants consented to personal jurisdiction in this Court pursuant to § 20.1 of the LCA.

18. This Court independently has personal jurisdiction over all Defendants under N.Y. C.P.L.R. §§ 301 and 302(a)(1). Each Defendant did business in New York, including by, among other things, negotiating and entering into the LCA and amendments thereto, making decisions and participating in critical discussions pursuant to the LCA, or otherwise engaging in the business of Dupixent commercialization in New York. For example, representatives of Sanofi Biotechnology SAS, sanofi-aventis U.S. LLC, and Genzyme Corporation participated in in-person meetings in New York and in teleconference meetings with Regeneron representatives in New York concerning the matters in dispute.

19. Defendants are also interrelated businesses such that they are agents, mere departments, or alter egos of each other and are subject to the same personal jurisdiction.

20. This Court has subject-matter jurisdiction over this action under 28 U.S.C. § 1332 because there is complete diversity of citizenship among the parties and, as detailed below, the amount in controversy exceeds $75,000, exclusive of interest and costs.

21. Because an actual controversy within the Court's jurisdiction exists, this Court may grant declaratory and injunctive relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

22. Defendants consented to venue in this Court pursuant to § 20.1 of the LCA. Venue is also proper in this District under 28 U.S.C. § 1391(b)(2) because Defendants' communications with Regeneron in this District form a substantial part of the events or

omissions giving rise to Regeneron's claims. In addition, for venue purposes, Defendants are deemed to reside in this District pursuant to 28 U.S.C. § 1391(c)(2).

III. FACTUAL ALLEGATIONS

23. Regeneron is a pioneer in the biopharmaceutical industry. In the 1990s and early 2000s, while larger pharmaceutical companies focused on traditional, small-molecule drugs (e.g., oral and topical medications), Regeneron was one of a few smaller biotechnology companies developing sophisticated large-molecule biologics. Biologics — including antibodies like Dupixent — are injectable proteins manufactured using live organisms. Biologics are much more difficult and expensive to develop and manufacture than small-molecule drugs.

24. When the biologics industry took off in the mid-2000s, many large pharmaceutical companies were left on the outside looking in. Faced with the prospect of being shut out of a promising new class of therapies, those large pharmaceutical companies sought to collaborate with cutting-edge biopharmaceutical companies like Regeneron that were pioneering biologic drugs.

A. Regeneron's and Defendants' Collaboration

25. In 2003, Regeneron entered into a collaboration with pharmaceutical company Aventis on a cancer drug Regeneron had invented. In 2004, Aventis merged with a Sanofi affiliate. As a result, Sanofi acquired Aventis's single-product collaboration with Regeneron.

26. At the time, Sanofi — one of the ten largest pharmaceutical companies in the world by sales and revenue but lacking expertise in biologics — was eager to invest in the biologics space and wanted access to biologic products like those in Regeneron's pipeline and the expertise in biotechnologies that Regeneron possessed. Regeneron was

an obvious choice for Sanofi's investment in biologics, and antibodies in particular. In 2007, Sanofi and Regeneron agreed to a collaboration in which Aventis Pharmaceuticals Inc. (the predecessor-in-interest to Sanofi Biotechnology SAS) would provide research funding over five years in exchange for the exclusive right to co-develop and co-commercialize any new biopharmaceuticals Regeneron managed to discover. Through this agreement, the parties set out to capitalize on the combination of their unique strengths and agreed to co-commercialize certain drugs if and when they were approved by regulators.

27. Regeneron, Aventis Pharmaceuticals Inc., and Sanofi-Aventis Amerique du Nord memorialized their collaboration in the original License and Collaboration Agreement ("Original LCA"), dated November 28, 2007. At the same time, Aventis Pharmaceuticals Inc. and Regeneron entered into a Discovery and Preclinical Development Agreement ("Original Discovery Agreement"), under which Regeneron would discover and create products to offer to Sanofi for joint development and commercialization. When Aventis Pharmaceuticals Inc. exercised its rights to work with Regeneron to develop and commercialize a product, that product became a "Licensed Product" under the Original LCA and was governed by its terms. Original LCA § 1.68.

28. Regeneron, Aventis Pharmaceuticals Inc., and Sanofi-Aventis Amerique du Nord expanded the scope and term of the collaboration in the Amended and Restated License and Collaboration Agreement ("LCA" or "Collaboration Agreement") and the Amended and Restated Discovery and Preclinical Development Agreement ("Amended Discovery Agreement"), both dated as of November 10, 2009. The Amended Discovery Agreement expired in 2017. The LCA remains in effect and will govern the collaboration until both parties

stop developing and commercializing any of the Licensed Products or until the Agreement is terminated as a result of a material breach by one of the parties.

29. One of the drugs the parties agreed to co-commercialize under the LCA is Dupixent, an injectable biologic used to treat atopic dermatitis, asthma, chronic obstructive pulmonary disease (or COPD), chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, and prurigo nodularis. Regeneron discovered Dupixent and submitted Dupixent's "Biologic License Application"[2] to the FDA, meaning that Regeneron is on file with the FDA as the owner of the drug. Under the LCA, Defendants paid most of the upfront development costs for Dupixent and are being paid back Regeneron's share of these development costs via the profits of Dupixent and other Licensed Products.

30. Dupixent is a blockbuster success: United States net sales of Dupixent grew from $776 million in 2018 to $8.8 billion in 2023, and in the first nine months of 2024 net sales in the United States have topped $7.6 billion. The total rebates and discounts Defendants have set for Dupixent are estimated to be a significant fraction of the total sales. By the end of August 2024, approximately one million patients were being treated with Dupixent globally across approved indications. Regeneron and Defendants co-commercialize the drug in the United States, the United Kingdom, Germany, Canada, the Netherlands, Japan, Spain, France, Austria, Italy, and Switzerland, and the parties share the profits from sales in all countries. As part of these co-commercialization efforts in the United States, Defendants enter into the PBM

[2] Before launching a biological product in the United States, the manufacturer must obtain a license by submitting a Biologic License Application to the FDA. *See* 42 U.S.C. § 262(a)(1)(A); 28 C.F.R. § 601.2(a).

Agreements to establish pricing terms, coverage, formulary positioning, access, and other terms for Dupixent.

B. Collaboration, Information Sharing, and Audit Rights Under the LCA

31. The LCA defines how Regeneron and Defendants work together to capitalize on Regeneron's scientific discoveries. In § 2.1, "Scope of Collaboration," the parties agreed to "cooperate in good faith to Develop, Manufacture and Commercialize Licensed Products . . . to optimize the commercial potential of each Licensed Product." Likewise, the "Collaboration Purpose" agreed to by the parties in § 3.1(b) is to "optimiz[e] the commercial potential of and financial returns from the Licensed Products . . . without regard to any other pharmaceutical product being developed or commercialized in the Field by or through a Party or any of its Affiliates."[3]

32. As the LCA's scope and purpose make clear, a significant aspect of the collaboration is the "Commercialization" of Licensed Products. Commercialization, as defined in the LCA, is a broad term that encompasses a wide range of activities relating to the marketing, promotion, and sale of pharmaceutical products, and the support activities associated with each of those functions, among other things. *See id.* § 1.20. The LCA defines "Commercialize" or "Commercialization" to mean,

> with respect to a Licensed Product, **any and all activities directed to** marketing, promoting . . . , detailing, distributing, importing, **offering for sale, having sold and/or selling such Licensed Product in the Field in the Territory**, **including**, without limitation, market research, **obtaining Pricing Approvals**, pre-launch marketing . . . , marketing and educational activities, post-Approval pharmacovigilance excluding pharmacovigilance for

[3] Under the LCA, the "Field" means "the treatment, prevention, palliation and/or diagnosis of any disease." LCA § 1.44.

> clinical trials other than Non-Approval Trials, sampling and Non-Approval Trials in the Territory.

Id. (emphases added).

33. Information sharing is vital for Regeneron and Defendants to optimize the commercial potential of each Licensed Product, including Dupixent. Information sharing builds trust between the parties, ensures effective collaboration, minimizes duplication, leverages collective expertise, and is an important check and balance on the parties' performance of their obligations under the LCA, among other things. Accordingly, Regeneron and Defendants have agreed to share certain commercial information about Licensed Products.

34. Specifically, § 6.4(b) of the LCA provides:

> Sanofi will provide Regeneron with **full access to material information** directly relating to the Commercialization of each Licensed Product in the Field, **including, without limitation, information relating to** anticipated launch dates, key market metrics, market research, and **sales**.

Id. § 6.4(b) (emphases added). Section 6.4(b) is not limited to written "material information." All material information related to the Commercialization of Dupixent is covered, regardless of whether it is conveyed in written or oral form. This broad provision, among others, facilitates the information sharing required not only for the parties' collaboration to be effective, but also to be conducted in accordance with the LCA.

35. Other provisions of the LCA similarly determine the guidelines within which the parties must pursue the Collaboration Purpose to "optimiz[e] the commercial potential of and financial returns" from Licensed Products. *Id.* § 3.1(b). For example, all pricing decisions must be made consistent with the Collaboration Purpose and in

accordance with the "Marketing Guidelines"[4] developed by the Joint Commercialization Committee. *See id.* §§ 3.4(b)(vi), 6.6. In addition, Section 6.11 of the LCA prohibits Defendants from "bundl[ing] or includ[ing] any Licensed Product as part of any multiple product offering or discount or pric[ing] the Licensed Products in a manner that (a) is reasonably likely to disadvantage a Licensed Product in order to benefit sales or prices of other products offered for sale by [Defendants] . . . , (b) is inconsistent with the Collaboration Purpose or (c) would result in pricing and discounting inconsistent with the applicable Marketing Guidelines." By imposing these restrictions, § 6.11 helps ensure the parties optimize the commercial potential of and financial returns from Licensed Products like Dupixent.

36. The mutual commitment to the Collaboration Purpose is crucial, as the LCA requires Regeneron and Sanofi to share the profits from Licensed Products. *Id.* § 9.4. To that end, the LCA directs Regeneron and Sanofi and its Affiliates to "keep proper books of record and account in which full, true and correct entries . . . shall be made for the purpose of determining the amounts payable or owed pursuant to th[e] Agreement." *Id.* § 14.1.

37. The LCA guarantees Regeneron and Defendants the right to audit "the books and records of the other Party and its Affiliates" to "verify[] the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under th[e LCA]." *Id.* § 14.2(a). When Regeneron or Defendants exercise this right, the other must "permit auditors

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[4] The LCA provides that the Joint Commercialization Committee "shall be responsible for . . . developing and updating, as necessary, global promotional guidelines for branding, positioning, core messages, and Promotional Material messages and Licensed Product pricing and rebate/discount guidelines," and "guidelines for determining the percentage of sales force compensation linked to sales of such Licensed Product" for "each Licensed Product, on a country-by-country basis for the Major Market Counties." LCA § 3.4(b)(vi). Collectively, these guidelines are referred to as the "Marketing Guidelines" for a particular product.

. . . to visit and inspect, . . . and to examine the books of record and account" if they relate to the LCA. *Id.* § 14.1.

38. It is a normal and customary practice for auditors to request and review third-party contracts, like the PBM Agreements, when evaluating rebates and other calculations related to commercializing pharmaceutical products. If certain rebates are supposed to apply only to Sanofi-owned products under the terms of the PBM Agreements, but such rebates are instead attributed to Dupixent in Defendants' books and records, the profit-sharing calculations between Defendants and Regeneron will be inaccurate. The auditors need to evaluate the PBM Agreements to guard against this and other similar types of inadvertent or intentional errors that significantly harm Regeneron.

C. Regeneron's and Defendants' Performance Under the LCA

39. Regeneron has consistently performed under the LCA, cooperating in good faith with Defendants to co-commercialize Dupixent and optimize the commercial potential of and financial returns from the drug.

40. Defendants, by contrast, have intentionally and continuously ignored their contractual obligations to share material information about the commercialization of Dupixent with Regeneron and its auditors. At the heart of this dispute are Defendants' contracts with payers, pharmacy benefit managers ("PBMs"), and other similar entities (together, "PBM Agreements"). PBMs serve as intermediaries between manufacturers, pharmacies, and insurance companies to negotiate rebates and discounts on coverage terms and formulary placement, among other things.[5] PBMs play a major industry role in

[5] A formulary is a list of drugs covered by a specific health insurance plan and the conditions associated with that coverage. A preferred formulary placement may help ensure that patients pay less out of pocket for the drug than if it was placed on a higher tier of the formulary.

the sale of pharmaceuticals and patient and provider access to them. The PBM Agreements are therefore critical to the commercialization of Dupixent.

41. Upon information and belief, the PBM Agreements contain complex terms related to coverage of, formulary positioning for, and access to Dupixent, as well as pricing, product offerings, services, and any rebates given by Defendants to the PBMs. Such Agreements involve written and potentially oral promises. By refusing to provide full access to the PBM Agreements, Defendants have violated Regeneron's rights under the LCA and have prejudiced Regeneron's ability to fully and meaningfully participate in key decisions regarding the commercialization of Dupixent.

42. ***First***, Defendants' refusal to provide Regeneron with "full access" to the PBM Agreements as required by LCA § 6.4(b) is impeding Regeneron's ability to exercise its bargained-for rights under the LCA, including its right to participate in the commercialization of Dupixent with the benefit of the material information it is entitled to receive. Regeneron has repeatedly requested full access to the PBM Agreements. But again and again, Defendants have refused, insisting that they need not provide Regeneron with "full access" to the PBM Agreements.

43. Sharing material information, like the PBM Agreements, is vital for Regeneron and Defendants to optimize Dupixent's commercial potential and effectuate the Collaboration Purpose set forth in the LCA. Among other things, information sharing builds trust between the parties, ensures effective collaboration, and leverages collective expertise. Information sharing also ensures Regeneron and Defendants can make well-informed decisions regarding Dupixent. And it is an important contractual safeguard: without information sharing, the parties could disadvantage each other for their own gain and evade detection.

44. Decisions about a blockbuster drug like Dupixent involve significant financial stakes due to the extensive costs associated with research and development, manufacturing, and commercialization, including marketing and distribution. Indeed, the discounts and rebates provided under the PBM Agreements for Dupixent are estimated to be a significant fraction of total Dupixent sales in recent years. Sanofi reported paying €7.6 billion in total rebates and discounts across all of its products in 2023, and Dupixent was far and away its biggest product that year, representing nearly a quarter of its net sales. Regeneron cannot fully participate in the commercialization of Dupixent when Defendants are improperly depriving Regeneron of full access to the PBM Agreements.

45. ***Second***, Defendants' refusal to produce the PBM Agreements is denying Regeneron its bargained-for right to have Defendants' books and records audited. On February 16, 2023, Regeneron invoked its contractual rights to audit Defendants for an inspection period spanning January 1, 2021 through December 31, 2022. During this audit, Regeneron asked Defendants to, at a minimum, provide Regeneron's outside auditors with an opportunity to inspect and examine the complete PBM Agreements under a non-disclosure agreement. But Defendants never allowed Regeneron's auditors to inspect full, unredacted copies of the Agreements.

46. In April 2023, Defendants offered to provide Regeneron's outside auditors — but not Regeneron itself — access only to discrete portions of the PBM Agreements that Defendants would unilaterally select. Defendants proposed limiting the outside auditors' access to the PBM Agreements to a screen-sharing technology controlled by Defendants' representatives, and insisted that Regeneron's outside auditors refrain from

capturing any image of the screen-shared Agreements. But again, that restrictive proposal falls far short of Defendants' obligations under the LCA.

47. In September 2023, Regeneron's audit for the two-year period ending on December 31, 2022 concluded without Defendants ever providing Regeneron or its outside auditors with "full access" to the PBM Agreements. Defendants' refusal to comply with LCA §§ 14.1 and 14.2 made it impossible for Regeneron's outside auditors to completely or meaningfully audit the financial information Defendants did provide.

48. Still, the partial audit revealed that a significant monetary adjustment, many multiples of $75,000, in favor of Regeneron was required to bring the collaboration's finances into alignment with the LCA. The parties further discovered that Defendants received a rebate attributable to Dupixent in 2021, but never reported it. Defendants did not produce the records revealing this mistake until after Regeneron requested them. As a result of this unreported rebate, Defendants were required to pay Regeneron an adjustment that far exceeds $75,000.

49. On or around September 18, 2024, Defendants, rather than comply with their contractual obligations, offered to provide Regeneron's outside auditors — but not Regeneron itself — redacted portions of the PBM Agreements. Defendants claimed that their ability to share any part of the PBM Agreements was subject to any confidentiality restrictions the PBMs might impose, and further insisted that Sanofi would have sole discretion regarding what portions of the ultimate audit report Regeneron could access.

50. This offer does not satisfy Defendants' contractual obligations and would not enable Regeneron or its auditors the access to the PBM Agreements they need to complete standard auditing procedures. If properly disclosed in their entirety, these contracts — which Regeneron and its auditors are each authorized to see under independent provisions of the LCA

— could reveal additional profit-sharing adjustments in favor of Regeneron. Regeneron's audit has already revealed inaccuracies in Sanofi's and its Affiliates' books. And given the blockbuster success of Dupixent, with U.S. net product sales topping $4.7 *billion* in 2021, $6.6 *billion* in 2022, $8.8 *billion* in 2023, and $7.6 *billion* in the first nine months of 2024, and substantial rebates, representing a significant fraction of the total sales in recent years, the additional reimbursements and profit-sharing adjustments in Regeneron's favor that the PBM Agreements may reveal could far exceed $75,000.

51. In addition, Defendants' violation of § 14.1 of the LCA has deprived Regeneron of the full value of the audit, which Regeneron has a contractual right to obtain and possess. *See* LCA § 14.2(a). Regeneron paid a flat fee of more than $75,000 for the audit but did not receive its full value, because the auditors were not able to evaluate the PBM Agreements. Thus, Regeneron has suffered and will continue to suffer damages exceeding $75,000 as a result of Defendants' breach of the LCA.

52. ***Third***, Defendants' impermissible conduct is hindering Regeneron's right to verify Sanofi and its Affiliates' compliance with other material provisions of the LCA.

53. In particular, Defendants' refusal to provide Regeneron with the PBM Agreements prevents Regeneron from learning whether Defendants are "bundling" Dupixent with other drugs in violation of the LCA.[6] *See* LCA § 6.11. A recent Senate report defined bundling as a practice whereby a manufacturer offers rebates and discounts for multiple products, but only if certain conditions are met by the PBM. For example, a manufacturer may group or leverage multiple products in order to offer rebates and

[6] The PBM Agreements are not the only type of evidence that may reflect whether Defendants are bundling Dupixent with other drugs. Communications between Defendants and PBMs, for example, whether oral or in writing, may also reveal evidence of bundling.

discounts on some or all of the components of a combined bundle, or condition rebates for one or more products on favorable treatment, such as preferred formulary placement by the PBM, on different products.

54. Sanofi has a history of bundling products in agreements with PBMs. According to a January 2021 United States Senate Committee on Finance report examining Sanofi's role in the rising cost of insulin, Sanofi has employed a strategy of bundling "unrelated products" in its negotiations with PBMs. For example, the report found that Sanofi bundled an epinephrine injection used to treat life-threatening allergic reactions with an insulin injection used to treat diabetes in order to secure formulary inclusion for both drugs. The report further found that Sanofi has "sought to include bundling agreements in several of its contracts" with PBMs.

55. In addition, a July 2024 Federal Trade Commission report includes an excerpt of a Sanofi rebate contract in which Sanofi bundled three different drugs. That bundle similarly secured preferred formulary coverage for Sanofi's products. The FTC report described the Sanofi rebate contract as "illustrative of numerous contracts with similar structures obtained from" PBMs.

56. Similarly, in October 2024 the State of Texas sued several PBMs, Sanofi, and other drug manufacturers. The lawsuit alleges that as recently as 2018, Sanofi executives, including Sanofi's CEO, met with a PBM with a stated objective to "[l]everage the entire Sanofi portfolio of assets to set the stage for future business development with [the PBM]." At that time, Sanofi's portfolio of assets included Dupixent.

57. The PBM Agreements Defendants are withholding establish pricing and commercialization terms (including any rebates or discounts) for Dupixent. And Defendants have told Regeneron that the PBM Agreements also establish pricing and commercialization

terms (including any rebates or discounts) for non-Licensed Products. Defendants' history of bundling products, their admission that the PBM Agreements pertain to both Dupixent and other drugs, and their repeated refusal to provide Regeneron and its designated auditors with full access to the PBM Agreements raise substantial concerns about Defendants' compliance with § 6.11 of the LCA.

58. A detailed analysis of the PBM Agreements, including contractual language, financial terms, and any written or oral side agreements or understandings, is required to determine whether Defendants are bundling Dupixent in violation of § 6.11 of the LCA. That provision prohibits Defendants from "bundl[ing] or includ[ing] any Licensed Product as part of any multiple product offering or discount or price the Licensed Products in a manner that (a) is reasonably likely to disadvantage a Licensed Product in order to benefit sales or prices of other products offered for sale by a Party or its Affiliates to such customer, (b) is inconsistent with the Collaboration Purpose or (c) would result in pricing and discounting inconsistent with the applicable Marketing Guidelines."

59. The LCA's prohibition on improper bundling ensures Regeneron does not bear the cost of Sanofi or its Affiliates' commercialization of non-Licensed Products. For example, and upon information and belief, PBMs sometimes demand during negotiations with manufacturers that the net prices of drugs in a multi-drug contract be reduced without specifying how that should be done. To illustrate, if a PBM required Defendants to provide a rebate of $100 million in a two-product contract (covering one Licensed Product and one non-Licensed Product), Defendants could evenly split the $100 million in rebates across both products. In that scenario, Defendants would be on the hook for

$75 million in rebate liability, and Regeneron would be responsible for $25 million, because Regeneron and Defendants split the costs of rebates for Licensed Products 50:50, but Defendants assume the entire cost of rebates for non-Licensed Products. Alternatively, Defendants could allocate the $100 million unevenly, which could cause Regeneron to pay more and Defendants to pay less than what an even split would require. For example, if Defendants allocate 98% of the rebate to the Licensed Product, then Defendants would saddle Regeneron with $49 million in rebate liability, making Defendants responsible for only $51 million in rebates (*i.e.*, all of the rebate liability for the non-Licensed Product and half of the rebate liability for the Licensed Product). That and other similar allocations would constitute an improper bundle and provide an economic advantage to Defendants at the Licensed Product's (and Regeneron's) expense. Absent a review and audit of the PBM agreements, Regeneron has no way to assure itself that Dupixent and other Licensed Products are not being improperly disadvantaged in these or other ways in the PBM Agreements. Regeneron's bargained-for rights in the LCA are designed to protect Regeneron from being duped by Defendants' potential manipulation of the economics and rebates provided under the PBM Agreements.

60. Similarly, Sanofi and its Affiliates would violate the LCA if the PBM Agreements included rebates or discounted pricing for Dupixent in exchange for a commitment by the PBMs to promote or give formulary preference to other Sanofi products. Defendants have made clear in their communications to investors that they are "particularly excited" about biologics that are "100% owned by Sanofi." One such biologic is amlitelimab, an antibody that Sanofi claims "has the potential to be a first-in-class treatment for a range of immune-mediated diseases and inflammatory disorders, including moderate-to-severe atopic dermatitis and asthma" — indications that Dupixent also treats. If Defendants provide PBMs with rebates for Dupixent in

order to secure benefits for their wholly-owned products like amlitelimab, Defendants would not be living up to their promise to optimize the commercial potential of Dupixent and financial returns from its sales, in violation of the Collaboration Purpose set forth in the LCA.

61. Indeed, on December 7, 2023, Sanofi CEO Paul Hudson commented on amlitelimab during a Sanofi "R&D Day" presentation in New York. He said it was "essential" that new drugs owned 100% by Sanofi — including amlitelimab — succeed so that Sanofi could throw all of the revenues from $10 billion in projected sales from those drugs "back into the mix at Sanofi . . . as Dupixent's expiry approaches." Hudson stated that Sanofi's wholly owned drugs and vaccines "have to run faster than Dupixent at the end" and went on to attempt to explain, "for clarity and for our great friends at Regeneron, Dupixent will grow and it will be a priority *right until its last day*."

62. Similarly, an interview published on October 16, 2024 quotes Sanofi's Head of Research and Development as stating, "We love Dupixent. It will grow to its final breath. But we have the measures internally to overcome that." When asked, "what's the single biggest opportunity for Sanofi" in the next five years, he responded, "Immunoscience, unequivocally. Dupixent gave us the reason to believe and the right to play. I think it's fair to say now, if not No. 1, we're certainly in the Premier League of immunoscience."

63. Contrary to these statements, there is no "last day" or "final breath" for Dupixent, nor is there a "last day" nor "final breath" for Defendants' obligations to optimize Dupixent's commercial potential pursuant to the LCA, without regard to Defendants' other, potentially competing products. These comments demonstrate

Defendants' intent to position their wholly-owned drugs to outrun Dupixent and abandon its obligations under the LCA as soon as a more profitable alternative is available. Regeneron's access to the PBM Agreements is a critical check and balance to prevent Defendants from gaming Regeneron.

64. In addition to violating Regeneron's rights under the LCA, Defendants' wrongful withholding of the PBM Agreements is preventing Regeneron from ensuring that Defendants are not engaged in any other actual or potential misconduct related to the commercialization of Dupixent. In September 2024, the FTC brought an action against the three largest PBMs for anticompetitive and unfair rebating practices that artificially inflated the list price of insulin. Although Sanofi is not named as a party, the FTC criticized Sanofi in a press release announcing the action:

> The FTC's Bureau of Competition makes clear in a statement issued today that the PBMs are not the only potentially culpable actors — the Bureau also remains deeply troubled by the role drug manufacturers like . . . Sanofi play in driving up list prices of life-saving medications like insulin.

The FTC warned "all drug manufacturers" that they "should be on notice that their participation in the type of conduct challenged here raises serious concerns, and that the Bureau of Competition may recommend suing drug manufacturers in any future enforcement actions."

65. Regeneron has an interest in reviewing the PBM Agreements to ensure that Defendants are not engaged in any actual or potential misconduct with respect to the commercialization of Dupixent.

66. Defendants' violations of the information-sharing provisions of the LCA are preventing Regeneron from confirming that the PBM Agreements comply with the LCA's terms and applicable laws. Regeneron bargained for, and Sanofi and its Affiliates agreed that Regeneron would have, "full access to material information directly relating to the

Commercialization of [Dupixent]." *See* LCA § 6.4(b). This right includes "full access" to the PBM Agreements. Access to the PBM Agreements is valuable because Regeneron cannot make fully informed decisions about Dupixent without it. The ability to make fully informed decisions about a drug that annually generates billions of dollars in sales is itself worth more than $75,000 to Regeneron.

IV. CLAIMS FOR RELIEF

COUNT I
BREACH OF CONTRACT

67. Regeneron incorporates the allegations set forth in the previous paragraphs of this Complaint as if fully set forth herein.

68. The LCA is a valid, binding contract among Regeneron, Sanofi Biotechnology SAS, and Sanofi-Aventis Amerique du Nord.

69. Regeneron performed under the LCA. In particular, Regeneron has cooperated with Defendants in good faith to commercialize Dupixent and optimize the commercial potential of and financial returns from the product.

70. In addition, Regeneron has used "all reasonable efforts, through [its] participation in the [Joint Steering Committee ("JSC")] in the first instance, to resolve [this] Legal Dispute."[7] *See* LCA § 10.3. The allegations asserted herein have been repeatedly discussed by the JSC, including at JSC meetings on October 23, 2023, December 1, 2023, and September 18, 2024. The JSC was unable to resolve the dispute.

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[7] LCA § 1.67 defines a "Legal Dispute" to "mean any dispute related to a Party's alleged failure to comply with this Agreement or the validity, breach, termination or interpretation of this Agreement."

71. At the JSC meeting on December 1, 2023, Regeneron and Defendants agreed to submit the Legal Dispute to the Executive Officers for possible resolution. Regeneron sent formal notice of that escalation on December 6, 2023. Regeneron's Executive Officer diligently and in good faith attempted to resolve the dispute, but the Executive Officers did not resolve the dispute within the time prescribed under the LCA. As a result, Regeneron is "free" under the LCA "to pursue any rights and remedies available to [it] at law, in equity or otherwise" in this Court. *Id.* § 10.3.

72. Sanofi Biotechnology SAS and Sanofi-Aventis Amerique du Nord chose to perform certain of their obligations under the LCA through their affiliates, Genzyme Corporation and sanofi-aventis U.S. LLC. Regeneron may therefore enforce the LCA against them. *See* LCA § 20.11.

73. Defendants have breached §§ 6.4(b) and 14.1 of the LCA by intentionally and continuously refusing to provide Regeneron and its auditors with full access to the PBM Agreements and any written or oral side agreements related to them. These contracts are material information directly related to the Commercialization of Dupixent, because their terms govern the pricing (including any rebates or discounts) and commercialization of Dupixent and necessarily affect payments due to Regeneron under the LCA. *See id.* §§ 1.20, 6.4(b). In addition, the PBM Agreements must be examined to verify the "accuracy of all financial, accounting and numerical information and calculations provided, and payment made, under th[e LCA]." *See id.* § 14.2(a).

74. Regeneron has suffered and will continue to suffer substantial harm as a result of Defendants' breach of the LCA, including, but not limited to, the loss of its bargained-for right to have "full access" to the PBM Agreements to make informed decisions about Dupixent — a drug

that annually generates billions of dollars in sales — as well as the loss of its full, bargained-for right to audit Defendants' books and records to, among other things, verify the accuracy of payments made under the LCA. Regeneron's most recent audit, to date, has exposed that Regeneron is entitled to substantial monetary adjustments, many multiples of $75,000, but the auditors cannot determine whether Regeneron is entitled to further adjustments, because Defendants are impermissibly withholding the information that would, if known, reveal whether such adjustments are required. And as a result of Defendants' improper conduct, Regeneron has not received the full value of the audit, which cost Regeneron more than $75,000.

COUNT II
REQUEST FOR DECLARATORY JUDGMENT

75. Regeneron incorporates the allegations set forth in the previous paragraphs of this Complaint as if fully set forth herein.

76. There is an actual, present, and justiciable controversy about Regeneron's and Defendants' rights under the LCA.

77. Under the LCA, Defendants are required to "provide Regeneron with full access to material information directly relating to the Commercialization of each Licensed Product in the Field, including, without limitation, information relating to . . . key market metrics . . . and sales." *See* LCA § 6.4(b). Commercialization is defined to include "any and all activities directed to marketing, promoting . . . , detailing, distributing, importing, offering for sale, having sold and/or selling" Licensed Products, including Dupixent. *Id.* § 1.20.

78. The PBM Agreements contain "material information directly relating to the Commercialization of [a] Licensed Product" — Dupixent — as the Agreements set

forth terms concerning pricing, coverage, and formulary positioning, as well as any discounts or rebates offered by Defendants to the relevant PBMs, which necessarily affect payments made under the LCA to Regeneron. *See id.* § 6.4(b); *see also id.* § 9.4(b), Schedule 2. Any side agreements between Defendants and the PBMs, regardless of whether they are written or oral agreements, are also "material information" to the extent they relate to the commercialization of Dupixent.

79. For these reasons, Defendants' outright refusal to provide Regeneron with "full access" to PBM Agreements for the sale of Licensed Products violates § 6.4(b) of the LCA.

80. In addition, Defendants' refusal to permit Regeneron's outside auditors to examine the complete PBM Agreements violates §§ 14.1 and 14.2(a) of the LCA, as such an examination is needed to verify the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under the LCA.

81. A judicial declaration under 28 U.S.C. § 2201 regarding Regeneron's and Defendants' rights under the LCA is therefore necessary and appropriate so that Regeneron may exercise its rights under the LCA.

82. Regeneron prays that the Court issue a declaratory judgment stating that Defendants are contractually obligated by § 6.4(b) of the LCA to provide Regeneron with full access to material information directly relating to the Commercialization of each Licensed Product in the Field, which includes, without limitation, any and all of Defendants' and their affiliates' complete, unredacted agreements with PBMs relating to the sale of Dupixent or any other Licensed Product (including any addenda, schedules, side agreements, and amendments), without regard to whether those agreements concern other products as well and without regard to whether those agreements are in written or oral form.

83. Regeneron also prays that the Court issue a declaratory judgment stating that Defendants are contractually obligated by § 14.1 of the LCA to permit contractually authorized auditors to examine any and all of Defendants' or their affiliates' complete, unredacted contracts with PBMs relating to the sale of Dupixent or any other Licensed Product (including any addenda, schedules, side agreements, and amendments), without regard to whether those agreements concern other products as well and without regard to whether those agreements are in written or oral form.

V. JURY DEMAND

84. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Regeneron demands a trial by jury on all issues so triable.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff Regeneron prays for the following relief:

a. The Court award specific performance pursuant to the LCA, entering an injunction ordering Defendants to provide Regeneron with any and all of Defendants' and their affiliates' complete, unredacted agreements with PBMs and payer entities relating to the sale of Dupixent or any other Licensed Product (including any addenda, schedules, side agreements, and amendments), without regard to whether those agreements concern other products as well and without regard to whether the agreements are in written or oral form;

b. The Court award specific performance pursuant to the LCA, entering an injunction ordering Defendants, and all affiliates, to permit Regeneron's auditors to examine any and all of Defendants' and their affiliates' complete, unredacted agreements with PBMs and payer entities relating to the sale of Dupixent or any other Licensed Product (including any addenda, schedules, side agreements, and

amendments), without regard to whether those agreements concern other products as well and without regard to whether the agreements are in written or oral form;

c. The Court enter a declaration that Defendants are contractually obligated by § 6.4(b) of the LCA to provide Regeneron with full access to material information directly relating to the Commercialization of each Licensed Product in the Field, including, without limitation, any and all of Defendants' and their affiliates' complete, unredacted agreements with PBMs and payer entities relating to the sale of Dupixent or any other Licensed Product (including any addenda, schedules, side agreements, and amendments), without regard to whether those agreements concern other products as well and without regard to whether the agreements are in written or oral form;

d. The Court enter a declaration that Defendants are contractually obligated by § 14.1 of the LCA to permit auditors, as provided in § 14.2, to examine any and all of Defendants' and their affiliates' complete, unredacted agreements with PBMs and payer entities relating to the sale of Dupixent or any other Licensed Product (including any addenda, schedules, side agreements, and amendments), without regard to whether those agreements concern other products as well and without regard to whether the agreements are in written or oral form;

e. That Regeneron recover all measure of damages allowable under statutory and common law;

f. That Regeneron recover its legal fees; and

g. The Court enter an order ordering such other and further relief as the Court deems appropriate.

Dated: November 18, 2024

Respectfully submitted,

/s/ *Andrew E. Goldsmith*
Andrew E. Goldsmith
Robert C. Klipper (*pro hac vice* to be filed)
Hilary M. Weaver (*pro hac vice* to be filed)
KELLOGG, HANSEN, TODD,
FIGEL & FREDERICK, P.L.L.C.
1615 M Street, N.W., Suite 400
Washington, D.C. 20036
(202) 326-7900
(202) 326-7999 (fax)
agoldsmith@kellogghansen.com
rklipper@kellogghansen.com
hweaver@kellogghansen.com

Counsel for Plaintiff